PRODUCT MONOGRAPH

PrPERJETA®

pertuzumab for injection

420 mg/14 mL vial

For Intravenous Infusion Only

Sterile Concentrate for Solution for Infusion

Antineoplastic

Professed Standard

Hoffmann-La Roche Limited
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PART III: CONSUMER INFORMATION

PrPERJETA®
pertuzumab for injection

This leaflet is part III of a three-part "Product Monograph" published when PERJETA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PERJETA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PERJETA, pronounced "per-JE-tah" is used to treat people with breast cancer when:
- there are a large number of "HER2-positive" cancer cells involved – your doctor will test for this.
- the cancer has spread to other parts of the body (metastasized)
- the cancer has not spread to other parts of the body and treatment is going to be given after surgery (treatment after surgery is called adjuvant therapy)

As well as PERJETA you will also receive HERCEPTIN and medicines called chemotherapy.

Information about these medicines is described in separate patient information leaflets. Ask your doctor or nurse to give you information about these other medicines.

What it does:
PERJETA is a type of medicine called a "monoclonal antibody" which attaches itself to specific targets in your body.

PERJETA recognizes and attaches to a protein in your body called "human epidermal growth factor 2" or HER2 for short. HER2 is found in large amounts on the surface of some cancer cells where it stimulates their growth. When PERJETA attaches to the HER2 cancer cells, it may slow or stop the cancer cells from growing, or may kill them.

When it should not be used:
Do not use PERJETA if you are allergic to this drug or to any ingredient in the formulation. See *"What the medicinal ingredient is"* and "*What the non-medicinal ingredients are"*. If you are not sure, talk to your doctor or nurse before you are given PERJETA.

PERJETA is not recommended for anyone under the age of 18 years because there is no information on how well it works in this age group.

What the medicinal ingredient is:
The medicinal ingredient in PERJETA is pertuzumab (pronounced per-TOOZ-ue-mab). Each vial of PERJETA contains 420 mg of pertuzumab

What the non-medicinal ingredients are:
Non-medicinal ingredients are (alphabetical order): glacial acetic acid, L-histidine, polysorbate 20, sucrose, water for injection.

What dosage forms it comes in:
PERJETA is a clear to slightly pearly (opalescent), colourless to pale brown solution for intravenous (IV) infusion. PERJETA is supplied as a single-use vial containing 14 mL preservative-free liquid concentrate, at a concentration of 30 mg/mL for dilution for intravenous infusion.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Heart Problems: PERJETA may cause heart problems, including those without symptoms (such as reduced heart function) and those with symptoms (such as congestive heart failure). Your health care provider may run tests to monitor your heart function before and during treatment with PERJETA. Based on test results your doctor may hold or discontinue treatment with PERJETA. See "*Serious side effects*" for more details about signs of heart problems to look out for.

Embryo-Fetal Toxicity: Exposure to PERJETA can result in embryo-fetal death and birth defects. Studies in animals have shown a reduction in the amount of amniotic fluid, delayed renal development, and death. Your health care provider will advise you of these risks and the need for effective contraception while you are taking PERJETA in combination with HERCEPTIN and 7 months after the last dose of treatment because of the length of time PERJETA and HERCEPTIN can remain in the body.

Hypersensitivity reactions / anaphylaxis and Infusion-related reactions: PERJETA has been associated with severe reactions. Deaths have been reported. You will be observed and carefully monitored during and after infusions. If you have a severe reaction, your doctor may need to completely stop your PERJETA treatment.

BEFORE you use PERJETA talk to your healthcare provider if:
- You have ever had heart problems (such as heart failure, heart attack, treatment for serious irregular heartbeats, uncontrolled high blood pressure) - your doctor will run tests to check if your heart is working properly
- You have ever had heart problems during previous treatment with HERCEPTIN
- You have ever had a chemotherapy medicine from the class called anthracycline, e.g. doxorubicin - these medicines can damage heart muscle and increase the risk of heart problems with PERJETA

If any of the above applies to you (or you are not sure), talk to your healthcare provider before you are given PERJETA.

Pregnancy, breast-feeding and contraception

- Before starting treatment, you must tell your healthcare provider if you are pregnant, think you may be pregnant or are planning to have a baby. You should also tell your healthcare provider if you are breast-feeding.
- Tell your healthcare provider straight away if you get pregnant during treatment with PERJETA and HERCEPTIN or during the 7 months after stopping treatment.
- Ask your healthcare provider about whether you can breast-feed during or after treatment with PERJETA.

PERJETA may harm the unborn baby. You should use effective contraception during treatment with PERJETA and HERCEPTIN and for 7 months after stopping treatment. If you are a male patient taking PERJETA with a female partner who can become pregnant you should use effective contraception during treatment with PERJETA and HERCEPTIN and for 7 months after stopping treatment. Talk to your healthcare provider about the best contraception for you.

INTERACTIONS WITH THIS MEDICATION

Before starting treatment, please tell your healthcare provider if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

It may take up to 7 months for PERJETA and HERCEPTIN to be removed from the body. Therefore, you should tell your doctor that you have had PERJETA if you start any new medication in the 7 months after stopping treatment.

PROPER USE OF THIS MEDICATION

Usual dose:
PERJETA will be given to you by your healthcare provider in a hospital or clinic.
- It is given by a drip into a vein (intravenous infusion) once every three weeks.
- The amount of medicine you are given and how long the infusion will last are different for the first, second and following doses.
- The number of infusions you will be given depends on how you respond to treatment and whether you are receiving treatment after surgery (adjuvant therapy) or for disease which has spread.
- PERJETA is given with other cancer treatments (HERCEPTIN and chemotherapy).

The first infusion:
- you will be given 840 mg of PERJETA over 60 minutes
- you will also be given HERCEPTIN and chemotherapy

For all following infusions, if the first infusion was well tolerated:
- you will be given 420 mg of PERJETA over 30 to 60 minutes
- you will also be given HERCEPTIN and chemotherapy

For further information on dosing of HERCEPTIN and chemotherapy (which can cause side effects as well), please refer to the package insert for these products. If you have questions about these medications, please ask your healthcare provider.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you forget or miss your appointment to receive PERJETA make another appointment as soon as possible.

If it has been 6 weeks or more since your last visit:
- a higher PERJETA dose of 840 mg will be given

You will then return to receiving a dose of 420mg PERJETA for following infusions.

If you stop having PERJETA
Do not stop having this medicine without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your healthcare provider.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Talk to your doctor, nurse or pharmacist if you are worried about side effects or find them very bothersome, and report any new or continuing symptoms to your doctor immediately. Your doctor will be able to tell you what to do and may be able to help you with these side effects.

Very common (may affect more than 1 in 10 people):
- hair loss
- dizziness
- loss of, or altered, taste
- producing more tears
- headache
- sore throat, red, sore or runny nose, flu-like symptoms and a fever
- feeling sick (nausea, vomiting)
- having less of an appetite
- nail problems
- rash, dry, itchy or acne like skin
- joint or muscle pain, muscle weakness
- weak, numb, tingling or prickling sensations mainly affecting the feet and legs
- pain in the body, arms, legs, and abdomen
- inflammation of your digestive tract (e.g. sore mouth)
- swollen ankles or other body parts due to your body holding onto too much water
- not being able to sleep

- decrease in the number of red and white blood cells – shown in a blood test
- fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- cough
- nose bleeds
- heartburn
- hot flushes

Common (may affect up to 1 in 10 people):
- inflammation of the nail bed where the nail and skin meet

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

If you experience any of the above symptoms after treatment with PERJETA has been stopped, you should consult your doctor immediately and inform them that you have previously been treated with PERJETA.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist immediately	
		Only if severe	In all cases
Very Common	Diarrhea	✓	
	Swelling of your face and throat with difficulty breathing, feeling sick (nausea), fever, chills, feeling tired, headache, loss of appetite, constipation and mouth ulcers.		✓
	Swollen ankles or other body parts		✓
	Shortness of breath and cough		✓
	Hot flushes		✓
	Loss of appetite	✓	
	Constipation	✓	
Common	Chest pain, nausea, discomfort radiating to the back, jaw, throat, or arm.		✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist immediately	
		Only if severe	In all cases
Rare	Vomiting, muscle cramps, numbness or tingling	✓	
	Decreased urination		✓

This is not a complete list of side effects. For any unexpected effects while taking PERJETA, contact your doctor or pharmacist.

HOW TO STORE IT

PERJETA will be stored by the health professionals at the hospital or clinic. The storage details are as follows:

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the vial and carton.
- Store vials in a refrigerator at 2-8°C.
- Keep vial in the outer carton in order to protect from light.
- Do not freeze or shake PERJETA.
- Do not use this medicine if you notice any particles in the liquid or it is the wrong colour (see "*What dosage forms it comes in")*.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

•Report online at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html
•Call toll-free at 1-866-234-2345
•Complete a Canada Vigilance Reporting Form and:
– Fax toll-free to 1-866-678-6789, or
– Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more detailed information, please also see Part I: WARNINGS AND PRECAUTIONS of the PERJETA product monograph. The product monograph is a document prepared for healthcare professionals and can be found at:
www.rochecanada.com
or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388.

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